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EXAMINER	
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1619	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,197	ELGER ET AL.	
	Examiner	Art Unit	
	IVAN GREENE	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7-9,11-18 and 20-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7-9,11-18 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/06/2010 in duplicate*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 1, 5, 7-9, 11-18 and 20-23 are currently pending. Claims 1, 7, 11-13, 18 and 21 have been presented in amended form.

The examiner has checked the amendment, submitted 07/06/2010, to the instant specification and finds no new matter has been introduced.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 07/06/2010 (presented in duplicate) was filed after the mailing date of the first office action on the merits but before mailing of a final rejection. No statement under 37 CFR 1.97(e) has been made but $180 fee has been charged. Accordingly, IDS submission is in compliance with the provisions of 37 CFR 1.97, and has been considered by the Examiner.

Rejections

Claim Rejections - 112 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New ground of rejection necessitated by amendment: Claims 7 and 21 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Claims 7 and 21 have been amended to include the limitation --the fat soluble active ingredient is present in a [...] animal oil or fat-- there is no support for this limitation in the specification as originally filed. The examiner cannot find support for the limitation that the "fat soluble active ingredient is present in a [...] animal oil or fat" in the specification at paragraph [0008] (as published) or in claims 6 or 7 as originally filed, as indicated by applicant in the reply dated 11/27/2009. Applicant should amend the claim to remove the new matter or specifically point out the reasoning used and support for these amendments in the specification.

Response to Arguments:

Applicant's arguments filed 07/06/2010 have been fully considered and are persuasive with regard to the limitation "a plant oil" but not persuasive with regard to the limitation "a animal oil or fat." Specifically, the support for:

> --A stable powderous formulation comprising a fat-soluble active ingredient [...] wherein [...] the fat-soluble active ingredient selected from the group consisting of vitamin A, vitamin D, vitamin E, vitamin K, a carotenoid, a polyunsaturated fatty acid, esters of any of the foregoing, and mixtures of any of the foregoing [and] additionally comprising a plant oil.--

is found in the original specification at page 1, lines 3-5; page 2, lines 7-15; page 3, lines 19-20; and page 4, lines 1-3. More specifically, the instant specification contemplates including a *triglyceride* as an *adjuvant,* and defines a triglyceride to include "a vegetable oil, such as corn oil, sunflower oil, soybean oil, safflower oil, rape seed oil, arachis oil, palm oil, palm kernel oil, cotton seed oil, or cocos oil." The instant specification does not contemplate the inclusion of an animal oil or fat as an ingredient other than the *active ingredient* which is "in a matrix formed from native lupin protein". Furthermore, the contemplation of an animal oil or fat is based upon the recitation of the originally presented claim 7, which recited "Stable powderous formulations comprising a fat-soluble active ingredient in a matrix of a

native lupin protein composition wherein the protein is cross-linked[1] [and] wherein the fat-soluble active ingredient is a plant or animal fat, particularly sunflower oil, palm oil or corn oil." And the, as originally presented did not contemplate combinations of any of those ingredients recited, or any combination of those ingredients. Therefore, because the instant recitation includes an "animal oil or fat" as other than the active ingredient, and the originally presented application did not contemplate a combination of an "animal oil or fat" with another active ingredient, the new matter rejection is maintained.

Applicant's argument that "As one skilled in the art knows, triglycerides are constituents of vegetable oils and animal fats" (p. 10, lines 6-7), is acknowledged. First, the disclosure that the "triglyceride is suitably a vegetable oil [...]" (page 4, lines 1-3), is scientifically incorrect[2] as applicant points out that triglycerides "are constituents of vegetable oils". Therefore the disclosure at page 4, lines 1-3 is taken as a definition of what applicant intended a triglyceride to be. And the definition did not include an animal oil or fat. Furthermore, while a person having ordinary skill in the art may recognize that an animal oil or fat may include triglycerides, this does nothing to show that applicant had possession of what is now clamed at the time the instantly claimed invention was made because, while it may have been obvious that vegetable oils contain vitamins, whether or not it would have been obvious is not germane to this new matter rejection because obviousness is not sufficient to show possession (*PowerOasis Inc. v. T-Mobile USA Inc.*, 86 USPQ2d 1385, 522 F3d 1299).

Claim Rejections – 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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[1] From original claim 1 the limitations of which, based upon dependency, claim 7 includes.
[2] A triglyceride is a component of vegetable oils which are mixtures that included mono- and/or di- glycerides, and fatty acids (without the glycerol moiety).

New ground of rejection necessitated by amendment: Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites --A stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition which *is a native lupin protein isolate* having a protein content of more than 90 wt. %-- and claim 5 recites --The formulation according to claim 1, wherein *the native lupin protein composition is selected from the group consisting of a lupin protein isolate* having a protein content of more than 90 wt. %, *a lupin protein concentrate* having a protein content of about 60-90 wt. %, *a lupin protein flour* having a protein content of about 40-60 wt. %, and mixtures of any of the foregoing.-- [emphasis added]. Claim 1 requires the "native lupin protein composition" is "a native lupin protein isolate having a protein content of more than 90 wt. %", however claim 5 allows for the "native lupin protein composition" to be a concentrate or a flour. It is unclear what exactly the "native lupin protein composition" should be. Appropriate clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 7-9, 15, 18 and 20-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over SCHNEIDER (US 5,356,636) in view of JONES (US 2002/0187185) and FITCHETT (WO 1999/11143).

Claim 14 remains rejected under 35 U.S.C. 103(a) as being unpatentable over SCHNEIDER (US 5,356,636) in view of JONES (US 2002/0187185) and FITCHETT (WO 1999/11143), as applied to claims 1-5, 7-9, 15 and 18-23 above, and further in view of TASHIRO (US 4,855,157), and as evidenced by the Merck Index (entries for "Sunflower Seed Oil," "corn oil" and "Oil Palm").

Claims 11-13, 16 and 17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over SCHNEIDER (US 5,356,636) in view of JONES (US 2002/0187185), FITCHETT (WO 1999/11143) and GERRARD (Trends in Food Science and Technology, 13, 2002, pp. 391-399); and as evidenced by SIEPAÏO (Journal of Agricultural and Food Chemistry, 1995, Vol. 43, pp. 1151-1156).

Response to Arguments:

Applicant's arguments filed 07/06/2010 have been fully considered but they are not persuasive.

At the outset it is noted that applicant' arguments are primarily directed to the references individually, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Additionally, regarding applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning[3], it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The premise on which applicant's arguments rest is that "the Examiner has erred in characterizing Jones as '[teaching] a gelatin protein substitute ***lupin***...." [emphasis in original], is acknowledged. The examiner disagrees with applicant's premise because JONES clearly teaches lupin protein as a gelatin substitute. The title of the JONES reference is "GELATIN SUBSTITUTE", and JONES claims a specific embodiment wherein the gelatin substitute is lupin protein as follows:

[3] Applicant's arguments p. 26, second paragraph; p. 27, last three lines; and page 38, lines 14-16.

13. A protein of vegetable origin suitable for use in capsule and microcapsule manufacture, which protein

(a) has a molecular weight of at least 40 kD; and

(b) is water soluble, whereby a clear aqueous solution can be formed that can produce a clear film on drying other than those identified or identifiable by the trademarks Tritisol and Tritisol XM.

14. A protein according to claim 13, having a weight average molecular weight of at least 200 kD.

15. A protein according to claim 13 or claim 14, wherein the vegetable is selected from wheat, soya, maize, rice, lupin, potato, jojoba, rape, pea, apricot kernel or evening primrose.

And JONES further teaches:

[0043] The preferred protein staring materials are 'isolates', since they contain the highest protein content. However, protein 'concentrates' and protein meals can also be used, although removal of carbohydrate may be necessary as a pre-treatment stage.

[0044] Examples of suitable vegetable-derived protein raw materials include, but are not limited to, wheat, soya, maize, rice, lupin, potato, jojoba, rape, pea, apricot kernel and evening primrose.

Thus, as a matter of fact, JONES does teach lupin as a gelatin substitute.

Applicant goes on to argue that JONES "teaches away" from using lupin protein[4] because of the teaching at paragraphs [0012] and [0013] that "Other vegetable proteins are commercially available in reasonably high purity, in the form of 'isolates', in which most of the carbohydrate present in the flour has been removed. Such isolates available include those derived from soya, wheat, pea and lupin. [...] However, such vegetable protein isolates are unsuitable for use in capsule production [...] because they are not fully soluble in water." Applicant's argument is not considered convincing because JONES clearly ***claims lupin protein*** (in claim 15).

Applicant further asserts that the examiner's statement of obviousness[5] is nothing but "conclusory statements" (p. 17, lines 17-18); and the rejection should have, but did not, explain on the record why a person having ordinary skill in the art would have modified the disclosures of SCHNEIDER, JONES and FITCHETT in the manner proposed by the examiner to arrived at the instantly clamed invention. In response the examiner argues that the record is clear. The record is clear SCHNEIDER teaches the all limitations of the instantly claimed invention except the native lupin protein isolate, a teaching that is provided by FITCHETT, and JONES provides the motivation to substitute the lupin protein for the gelatin in the invention of SCHNEIDER, namely, religious and vegetarian pressure to not use animal based products (i.e. gelatin), and concerns about the risk of contracting bovine spongiform encephalopathy (i.e. mad cow disease) from the use of gelatin. If further clarification is needed applicant can contact the examiner as per the information provided at the end of each office action.

Applicant's argument's in the last paragraph on page 19, that SCHNEIDER does not disclose, suggest, or provide motivation for the instantly claimed invention, are acknowledged. However, the presented arguments are against SCHNEIDER alone and there is no rejection of record over SCHNEIDER alone. Thus, these arguments cannot show nonobviousness of the instantly claimed invention.

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[4] Applicant's arguments p. 16, paragraph 2; p. 20, line 17; p. 21, last paragraph; p. 26, line 2; and p. 35, lines 19-20.

Applicant's argument's in the last paragraph on page 20, that JONES does not disclose, suggest, or provide motivation for the instantly claimed invention, are acknowledged. However, the presented arguments are against JONES alone and there is no rejection of record over JONES alone. Thus, these arguments cannot show nonobviousness of the instantly claimed invention.

Applicant's arguments that the teaching of JONES that "Other vegetable proteins are commercially available in reasonably high purity, in the form of 'isolates', in which most of the carbohydrate present in the flour has been removed. Such isolates available include those derived from soya, wheat, pea and lupin. [...] However, such vegetable protein isolates are unsuitable for use in capsule production [...] because they are not fully soluble in water." (at paragraphs [0012] & [0013]), is acknowledged. In response the examiner argues that this is not a teaching away because JONES is merely discussing the prior art and problems encountered therein. Furthermore, this cannot be considered a teaching away because JONES goes on to claim lupin protein as an element of their invention (see discussion above). The examiner further notes the reasoning given by JONES in the above quoted paragraph, namely, "they are not fully soluble in water" is not applicable to the instantly claimed invention because this is not a claimed limitation, and in fact applicant's disclosed example 2 "was insoluble in hot water" (instant specification p. 4, last paragraph).

Applicant's argument's in the last paragraph on page 22, that FITCHETT does not disclose, suggest, or provide motivation for the instantly claimed invention, are acknowledged. However, the presented arguments are against FITCHETT alone and there is no rejection of record over FITCHETT alone. Thus, these arguments cannot show nonobviousness of the instantly claimed invention.

Applicant's argument that JONES lacks any enabling disclosure of preparing a powderous formulation (p. 21, lines 14-15), is acknowledged. However, this argument is against JONES alone and

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[5] See "Non-Final Rejection" dated 02/03/2010 at paragraph bridging pages 8 and 9.

there is no rejection of record over JONES alone. Thus, this argument cannot show nonobviousness of the instantly claimed invention.

Applicant's argument that FITCHETT lacks any enabling disclosure of preparing a powderous formulation in which the native lupin protein isolate of the matrix is cross-linked (p. 22, lines 11-14), is acknowledged. However, this argument is against FITCHETT alone and there is no rejection of record over FITCHETT alone. Thus, this argument cannot show nonobviousness of the instantly claimed invention.

Applicant's argument's directed to the obviousness rationale "obvious to try" (MPEP § 2143 (E)) (p. 26, line 16 through p. 27), are confusing because no "obvious to try" rationale has been made of record. The examiner requests that applicant specifically point out where in the record the "obvious to try" rationale was invoked.

Applicant's argument's in the last paragraph on page 30, that TASHIRO provides no disclosure, suggestion, or motivation to produce the instantly claimed invention, are acknowledged. However, the presented arguments are against TASHIRO alone and there is no rejection of record over TASHIRO alone. Thus, these arguments cannot show nonobviousness of the instantly claimed invention.

Applicant's arguments regarding one of ordinary skill in the art having a reasonable expectation of success in producing the instantly claimed invention, specifically in cross-linking of the lupin protein (p. line 20 to p. 38, line 13), are acknowledged. The examiner maintains that a person having ordinary skill in the art would have had a reasonable expectation of success in using the lupin protein taught by FITCHETT in the invention of SCHNEIDER because the reference GERRARD, a review of the art of protein-protein cross-linking, teaches "food protein, either native or denatured" can be cross-linked via a number of different chemical reactions (p. 392, figure 1, and accompanying text). Furthermore, the teaching in SIEPAIO that lupin actually naturally contains the cross-linking enzyme transglutaminase further supports the examiners argument that a person having ordinary skill in the art would have had a

reasonable expectation of success in using the lupin protein in a cross-linking process. The fact that the "amount" of transglutaminase naturally occurring in lupin is not sufficient to produce a cross-linked product as currently claimed (applicant's arguments page 38, paragraph two) is immaterial because JONES teaches using transglutaminase at paragraph [0040], which is the teaching that the examiner is relying to support the rejection.

Applicant's statement that "Gerrard's general disclosure of the use of transglutaminase in the context of a Maillard reaction" is a mischaracterization of the reference because GERRARD teaches a section on "Crosslinks derived from the Maillard reaction" on page 393 and a separate section on "Crosslinks formed via transglutaminase catalysis" on page 394.

Nonstatutory Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

New ground of rejection necessitated by amendment: Claims 1, 7-9, 11, 13-15, 17, 18 and 20-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 8, 12-14, 16, 17 and 21 of copending Application No. 10/564,635 in view of JONES (US 2002/0187185) and FITCHETT (WO 1999/11143).

Instant claim 1 recites, a stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt. %, wherein the protein in the matrix is cross-linked and the fat-soluble active ingredient is selected from the group consisting of vitamin A, D, E or K, a carotenoid, a polyunsaturated fatty acid, esters of any of the foregoing, and mixtures of any of the foregoing. Instant claim 11 recites, a process for the preparation of a formulation comprising preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt. %, wherein a reducing sugar is added and the composition is submitted cross-linking by heating. Instant claim 7 recites the formulation [...] comprising additionally a plant or animal oil or fat. Instant claim 8 recites formulation [...] comprising additionally a reducing sugar. Instant claim 15 limits the reducing sugar to glucose, fructose or xylose. Instant claim 13 is similar to instant claim 11 except the limitation "cross-linking by heating" is replaced with "converting the emulsion to a dry powder." Instant claim 18 recites a stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt. %, wherein the protein in the matrix is cross-linked with a reducing sugar. Instant claims 20-22 recite limitations similar to claims 1 (the active ingredients), claim 7 and claim 15, respectively.

Copending '635 claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix of milk protein composition, wherein the protein is thermally cross-linked with a reducing-sugar. Copending '635 claims 6 recites the formulation additionally comprises a plant protein; and copending '635 claim 8 recites formulations which further comprise plant protein which is obtained from [...] *lupin protein*. Copending '635 claim 12 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or a carotenoid, or a polyunsaturated fatty acid; copending '635 claim 13 recites formulations wherein the fat-soluble active ingredient is mixed with a plant or animal fat. Copending '635 claim 14 further limits the reducing sugar to glucose, fructose, saccharose or xylose. Copending '635 claim 17 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the milk protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein with heat treatment. Copending '635 claim 21 further limits the plant oil to sunflower oil, palm oil, or corn oil. And copending '635 claim 16 claims a food, beverage, animal feeds, cosmetics or drugs comprising said formulations.

The difference between Copending '635 and the instant claimed invention is that copending '635 does not explicitly teach the use of a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt. %.

FITCHETT teaches lupin protein compositions (abstract), which are vegetable protein concentrates (50-90% protein), and protein isolates (90+% protein) are widely used in the food industry (pg. 1, lines 9-15). And JONES provides the motivation to substitute the lupin protein for the milk protein in '635, namely, religious and vegetarian pressure to not use animal based products (i.e. milk protein), and concerns about the risk of contracting bovine spongiform encephalopathy (i.e. mad cow disease) from the use of milk protein ([0006]).

It would have been *prima facie* obvious to combine copending '635 with the teachings of FITCHETT and produce the instantly claimed invention because, as suggested by JONES, there is consumer pressure on producers to utilize vegetable based proteins. Furthermore, the lupin protein of FITCHETT would provide an added nutritive value to copending '635 and produce a more desirable product. A person having ordinary skill in the art would have been motivated to substitute the milk protein of '635 with the lupin protein of the instant application because it would provide access to a new market of consumers for which the milk protein would be unacceptable (e. g. vegans, lactose intolerant consumers). A person having ordinary skill in the art would have had a reasonable expectation of success in producing the instantly claimed invention from the clams of '635 because those claims recite include lupin protein (claim 8).

This is a provisional obviousness-type double patenting rejection.

Applicant is reminded that the merits of a provisional obviousness-type double patenting rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue. *In re Mott*, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); *In re Wetterau*, 356 F.2d 556, 148 USPQ 499 (CCPA 1966).

Response to Arguments:

Applicant's arguments filed 07/06/2010 have been fully considered but they are moot in view of the new grounds of rejection.

Conclusion

Claims 1, 5, 7-9, 11-18 and 20-23 are currently pending and have been presented for examination on the merits. Claims 7 and 21 remain rejected under 35 U.S.C. 112, first paragraph (new matter); claim 5 is rejected under 35 U.S.C. 112, second paragraph; claims 1, 5, 7-9, 11-18 and 20-23 remain rejected under 35 U.S.C. 103(a); and claims continue to be provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/564,635. No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-5868. The examiner can normally be reached on Monday through Thursday 7AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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